

REMARKS

I. Detailed Action

A. Election/Restrictions

Applicants affirm the election of Group I, claims 1-12, 23, 24, 25, 30-36, 43-44, and 45-51. Applicants acknowledge that claims 13-22, 26-29 and 37-42 are withdrawn from further consideration by the Examiner. Applicants wish to respectfully point out what Applicants believe to be a typographical error. The Examiner states that claims 27-42 are withdrawn from consideration. Applicants believe that the Examiner meant claims 37-42.

B. Information Disclosure Statement

Applicants acknowledge that the information disclosure statement filed on 11/3/04 fails to comply with the provisions of 37 C.F.R. 1.97, 1.98 and MPEP § 609 because the citation does not provide a full citation of the reference including page numbers of the article. Applicants further acknowledge that the article has been considered.

C. Claim Objections

Claims 1, 2, 3, 4, 5, 30, 31, 32, 43, 44, 45, 46, 47 and 48 are objected to as reciting non-elected subject matter. Applicants have amended these claims to remove the non-elected subject matter, thereby alleviating this objection.

II. Claim Rejections

A. 35 U.S.C. § 112, second paragraph

Claims 1-12, 23-25, 30-36 and 43-51 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

With regard to claims 1-12 and 23-25, the Examiner states that the terms "favorable muscle growth and/or meat quality", "favorable breeding traits", "favorable combination of traits for muscle growth and/or meat quality" and "favorable meat quality" are not clear. The Examiner states that with respect to claim 1, it is not clear if the "favorable" is meant to modify both muscle growth and meat quality. Applicants have amended claim 1 to recite the term "favorable" prior to meat quality to alleviate this concern. The Examiner further states that "because whether or not a particular trait is favorable is entirely context dependent, and is subjective in nature, it is unclear what the recited polymorphisms are associated with."

Applicants respectfully traverse this rejection. The specification defines the meaning of "favorable" traits. As taught by the specification:

As used herein "favorable meat quality and/or muscle growth" refers to favorable meat quality, heavy muscling, and/or likelihood of skeletal muscle cramping disease. It means a significant increase or decrease (improvement) in one of many measurable meat quality or muscle growth traits (heavy muscling and/or skeletal muscle cramping disease) above the mean of a given population, so that this information can be used to achieve a uniform population which is optimized for meat quality and/ or muscle growth, this may include an increase in some traits or a decrease in others depending on the desired characteristics. (Specification, p. 19)

The specification also discusses favorable genetic traits as traits which are useful in animal breeding as taught by the specification, i.e. breeding traits. (Specification, p. 5). The Board of Patent Appeals and Interferences recently affirmed similar "subjective" language which was found to be terms of art and understood by a person skilled in the relevant art. *See Ex parte Carlson*, p. 16 (B.P.A.I. 2005). Appeal No. 2004-2317, Application No. 09/771,938 (copy attached) which held that the terms "yield enhancement", "improved nutritional quality", and "enhanced yield stability" were found to be acceptable under 35 U.S.C. § 112:

The fact that some claim language is not mathematically precise does not per se render the claim indefinite: Seattle Box. As set forth in Shatterproof Glass, "[i]f

the claims, read in light of the specifications, reasonably apprise those skilled in the art both of the utilization and the scope of the invention and if the language is as precise as the subject matter permits, the courts demand no more.

In that plant breeding case the Board noted that when a word of degree is used, then the specification must provide a standard for measuring that degree. The board agreed with the Appellant that these terms would be understood by one of skill in the art to be relative to a plant lacking the locus.

This case is directly analogous. This case is an animal breeding case where the term is not only defined very specifically in the text (i.e. as measured against the mean of a given population) but also one of skill in the art would also understand that comparison could also be made relative to a plant lacking the allele in question.

The specification thus teaches the meaning of the terms "favorable muscle growth and/or meat quality", "favorable breeding traits", "favorable combination of traits for muscle growth and/or meat quality" and "favorable meat quality". Applicants therefore submit that claims 1-12 and 23-25 are in condition for allowance.

With regard to claims 1-12, 23-25, 30-36, 43-44 and 47-51 the Examiner states that the terms "assaying for the presence of a polymorphism" and "presence of a polymorphism" are indefinite "because it is unclear from the claim how to identify 'the presence of a polymorphism'". The Examiner further states that "[a] polymorphism is a difference in a nucleotide sequence among individuals, and if one is looking at the genetic material from 'an animal' it is unclear how one would identify a polymorphism within the individual."

Applicants respectfully traverse this rejection. The specification teaches that a polymorphism is a genetic means by which a genotype which is indicative of the presence of a particular phenotype can be identified. (*See, e.g.,* Specification, p. 21). Techniques for assaying

for the presence of a polymorphism in a single individual are taught in the specification. (Specification, pp. 21-32). The specification thus teaches the meaning of the terms "assaying for the presence of a polymorphism" and "presence of a polymorphism". Applicants therefore submit that claims 1-12, 23-25, 30-36, 43-44 and 47-51 are in condition for allowance. Applicant has also amended claim 1 to recite "polymorphic allele" in an attempt to expedite prosecution.

With regard to claims 31 and 32, the Examiner states that "it is not clear how the language 'or an insertion or deletion' is related to the other method steps in recited in claim 31.

Applicants have amended claim 31 to clarify the meaning of the term "'or an insertion or deletion". Claim 32 depends from claim 31. Therefore Applicants submit that claims 31 and 32 are now in allowable form.

With regard to claims 45 and 46, the Examiner states that "it is not clear how the method steps in the claims accomplish the goal of the claims as set forth in the preamble of claim 45." The Examiner further states "there is no recitation in the claim that makes a connection between the presence or absence of the restriction sites and a favorable combination of traits."

Applicants have amended claims 45 to make clear how the method steps in the claims accomplish the goal of the claims as set forth in the preamble of claim 45. Claim 46 depends from claim 45. Therefore Applicants submit that claims 45 and 46 are now in allowable form.

With regards to claims 47 and 48, the Examiner states that the claims are indefinite "over the recitation of sequence identifiers in parenthesis within the claim, because it is not clear if these are intended to set forth positive limitations . . . or if they are meant to give possible examples of the recited region."

Applicants have amended claim 47 to clarify Applicants use of the sequence identifiers. Claim 48 depends from claim 47. Applicants therefore submit that claims 47 and 48 is in condition for allowance.

With regard to claims 49, 50 and 51, the Examiner states that the terms are indefinite "because it is not clear which gene the recited polymorphisms are within, since the claim recites a MspAII and a 9 bp insertion/deletion but does not provide any context for these polymorphisms."

Applicants have amended claim 49 to recite the CKM gene, thereby alleviating this rejection. Claims 50 and 51 depend from claim 49. Applicants therefore submit that claims 49-51 are in condition for allowance.

With regard to claim 50, the Examiner states that the claim is indefinite "because it is unclear what the arbitrary identifiers '1-1, 1-2, and 2-2' mean."

Applicants respectfully traverse this rejection. The Specification identifies the terms "1-1", "1-2" and "2-2" to refer to three of the four possible haplotypes. (Specification, Example 10, p. 57). The specification thus teaches the meaning of the terms "1-1", "1-2", and "2-2". Applicants therefore submit that claim 50 is in condition for allowance.

B. 35 U.S.C. § 112, first paragraph: Enablement

Claims 1-12, 23-25, 30-36 and 43-51 stand rejected under 35 U.S.C. § 112, first paragraph as containing subject matter which was not describe in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The Examiner states that it is statistically unpredictable whether a particular polymorphism is associated with the traits in question and that there is no evidence of other polymorphisms existing in other animals. The Examiner next states that the

claim scope is overbroad because it encompasses every animal species. Finally, the Examiner states that an undue amount of experimentation is necessary to screen animals for a polymorphism because there is no "consistent guidance with regard to precisely which polymorphism would be indicative of what trait in pigs".

Applicants respectfully traverse this rejection. Applicants have amended independent claim 1 to require that a polymorphism is identified and then "correlating whether a statistically significant association exists between said polymorphism and favorable muscle growth and/or meat quality in an animal of a particular breed, strain, population, or group whereby said animal can be characterized for said marker". Independent claims 30, 45 and 50 also requires that the polymorphism within the CKM gene is correlated or associated with the traits in question. These claims are commensurate in scope with what is taught in the specification.

Applicant's invention relates to and teaches the unexpected and unequivocal finding that variation in the creatine kinase-muscle (CKM) gene is associated with favorable muscle growth, favorable meat quality, and breeding traits. Applicants have identified polymorphisms that exist within the CKM gene which allow one skilled in the art to select those animals which are likely to produce these desired traits. The identification of additional polymorphisms in the CKM gene is routine to one skilled in the art and there is ample description in the specification for identification of other polymorphisms. Experimentation is permissible if it is routine and if guidance is provided directing such experimentation such that one skilled in the art would be able to practice an embodiment of the invention. *Ex Parte Forman*, 230 U.S.P.Q 546, 547 (Bd. Pat. App. & Int'l 1986).

The initial step in identifying a polymorphism involves isolation of an animal's DNA. (Specification, p. 21). The DNA is then assayed for the presence of a polymorphism using techniques well known in the art:

Any method of identifying the presence or absence of these markers may be used, including, for example, single-strand conformation polymorphism (SSCP) analysis, base excision sequence scanning (BESS), RFLP analysis, heteroduplex analysis, denaturing gradient gel electrophoresis, and temperature gradient electrophoresis, allelic PCR, ligase chain reaction direct sequencing, mini sequencing, nucleic acid hybridization, micro-array-type detection of the CKM, SCN4 α , or LDH α gene, or other linked sequences of the CKM, SCN4 α , or LDH α gene. Also within the scope of the invention includes assaying for protein conformational or sequences changes which occur in the presence of this polymorphism. The polymorphism may or may not be the causative mutation but will be indicative of the presence of this change and one may assay for the genetic or protein bases for the phenotypic difference. (Specification, p. 21)

A specific example of isolating and identifying a polymorphism within the CKM is provided in Examples 1-3 and 9, pages 34-40, 48-57.

Moreover, because the Applicants have identified at least three polymorphisms within the CKM gene, the isolation of additional polymorphisms is now both expected and routine. (Specification, p. 33). Once a polymorphism within the CKM receptor gene has been identified, one skilled in the art would be able to perform routine experimentation in order to associate that polymorphism with favorable muscle growth, favorable meat quality, and/or favorable breeding traits. An example of an association study is provided in the specification. See Example 9, pages 48-57.

Further, with respect to the Examiner's argument that the claims scope is overbroad because it encompasses animals other than pigs, the specification teaches that the CKM gene sequence is highly conserved and thus that other animals with CKM genes will contain the same quality of being able to use variants within the CKM gene as a marker for favorable muscle growth, favorable meat quality, and breeding traits:

In another embodiment, the invention comprises a method for identifying a genetic marker for meat quality, heavy muscling, and/or skeletal muscle cramping disease in any particular economic animal other than a pig. Based upon the highly conserved nature of this gene among different animals and the location of the polymorphisms within these highly conserved regions, is it expected that with no more than routine testing as described herein that these markers can be applied to different animal species to select for meat quality, heavy muscling, and/or skeletal muscle cramping disease based on the teachings herein. Male and female animals of the same breed or breed cross or similar genetic lineage are bred, and the meat quality, heavy muscling, and/or skeletal muscle cramping disease produced by each animal is determined and correlated. For other animals in which sequences are available a BLAST comparison of sequences may be used to ascertain whether the particular allele is analogous to the one disclosed herein. The analogous polymorphism will be present in other animals and in other closely related genes. (Specification, p. 8)

Evidence of this is found in the fact that amplification primers may be designed to test for the presence of the identified polymorphisms using pig or human CDM sequences due to the high homology in the region surrounding the identified polymorphisms. (Specification, p. 31).

In light of the above amendments and remarks, Applicant respectfully requests reconsideration and withdrawal of the rejections to claims 1-12, 23-25, 30-36 and 43-51 under 35 U.S.C. § 112, first paragraph.

C. 35 U.S.C. § 112, first paragraph: Written Description

Claims 1-7, 9, 11, 23-25, 30-33, 43-44 and 47-51 stand rejected as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The Examiner states that the genus covered by Applicants' claims includes "an enormous number of polymorphisms for which no written description is provided in the specification."

Applicants respectfully traverse this rejection. Applicants' claimed invention relates to the association of the CKM gene to the phenotypic traits of favorable muscle growth, favorable

meat quality, and breeding traits. Thus, each species within the genus encompassed by Applicants' claims all share the common attribute of being quantitative trait loci that have a measurable effect on these phenotypic traits.

The Federal Circuit has stated that a genus claim may be adequately described where there is a "recitation of structural features common to the members of the genus." *Regents of University of California v. Eli Lilly*, 119 F.3d 1550, 1569 (Fed. Cir. 1997). Moreover, the USPTO's Written Description Guidelines states that a sufficient variety of species has been described to reflect variation within the genus where "one of skill in the art would recognize that the applicant was in possession of the necessary common attributes or features of the elements possessed by the member of the genus in view of the species disclosed."

The structural feature common to all members of the genus is the CKM gene. Further, in order to fall within the scope of Applicants invention, the variant screened for within the CKM gene, or a region therein, must have the function of being associated with favorable muscle growth, favorable meat quality, or favorable breeding traits.

Identification of the relevant polymorphism is the means by which one practices the invention, i.e., the association between the CKM gene and favorable muscle growth, favorable meat quality, or favorable breeding traits. The specification teaches at least three polymorphisms that have been identified which correlate with a phenotypic difference in favorable muscle growth, favorable meat quality, and breeding traits. These polymorphisms are identified in the specification using the restriction enzymes MspAII and BamHI, and by a 9 base pair insertion/deletion in the CKM gene. See specification, Examples 1-3, pages 34-40. Since one of skill in the art would recognize that Appellant's were in possession of the common attribute within the genus, i.e., the association between the CKM gene and the phenotypic traits of

favorable muscle growth, favorable meat quality, and favorable breeding traits, Applicants have adequately described a representative number of species.

In light of the above remarks, Applicants respectfully request reconsideration and withdrawal of the rejections to claims 1-7, 9, 11, 23-25, 30-33, 43-44 and 47-51 under 35 U.S.C. § 112, first paragraph.

D. 35 U.S.C. § 102(b)

Claim 47 stands rejected under 35 U.S.C. § 102(b) as being anticipated by Benfield et al. The Examiner states Benfield teaches "a method comprising the steps of obtaining a genetic sample from an animal and assaying for the presence of a polymorphism located in the CKM gene in the 5' untranslated region of said gene".

Applicants respectfully traverse this rejection. Benfield teaches the sequencing of the promoter region of the rat CKM gene. (Benfeld, p. 235-237, Figure 7). Benfeld does not teach the identification of polymorphisms within the CKM gene. (*Id.*) Accordingly, Benfeld can not anticipate claim 47. Applicants therefore respectfully request reconsideration and withdrawal of the rejection to claim 47 under 35 U.S.C. § 102(b) as being anticipated by Benfield et al.

III. Conclusion

In light of the above remarks, Applicants respectfully assert that claims 1-51 are now in condition for allowance. Applicants respectfully request reconsideration and withdrawal of the above rejections. If it is felt that it would aid in prosecution, the Examiner is invited to contact the undersigned at the number indicated to discuss any outstanding issues.

No fees are believed to be due in connection with this amendment; however, consider this a request for any inadvertently omitted, and charge any additional fees to Deposit Account No. 26-0084.

Reconsideration and allowance is respectfully requested.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Heidi S. Nebel". The signature is fluid and cursive, with the first name being more prominent.

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